IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	
Olivier De Lacharriere et al.	Group Art Unit: 1615
Application No.: 09/735,638	Examiner: GOLLAMUDI S KISHORE
Filed: December 14, 2000	Confirmation No.: 6191
For: USE OF SUBSTANCE P ANTAGONISTS IN A COSMETIC COMPOSITION, AND THE COMPOSITION THUS OBTAINED	

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Olivier De Lacharrière, hereby state as follows:

1) I was awarded a doctorate in medicine from the University of René Descarte in Paris, France in 1982.

2) Currently I am the Director of the Prospective Clinical Research in the Department of Advanced Reserch-Life Sciences at L'ORÉAL.

3) My *curriculum vitae*, research experience and list of publications are attached hereto as Appendix I.

4) I am aware that the Examiner in the above-identified application has concluded that the pending claims are anticipated or obvious under 35 U.S.C. §§ 102(b)/103(a) by WO 93/14084; and the combination of Wallengren (contact dermatitis), Wallengren (BR. J. Dermatitis) in combination with WO 83/01252, WO 93/14084 individually or in combination. For at least the reasons that follow, I respectfully disagree.

5) Both of the Wallengren articles (1988 and 1991) relate to an **allergic** condition such as contact dermatitis or irritant delayed reaction. WO 83/01252 relates to a drug based on a substance P antagonist for the treatment of inflammation or diseases showing inflammatory conditions. Finally, WO 93/14084 relates to piperidine derivatives showing substance P antagonist activity wherein the derivatives may be used for their analgesic or anti-inflammatory properties.

6) After studying the above references, I conclude that (i) only immunological reaction of urticaria may be suppressed by substance P antagonist (Wallengreen, 1988, abstract), (ii) the pretreatement with spantide, a substance P antagonist, does not affected irritant reaction (Wallengreen, 1991, p.327, left column, line 19) and that (iii) piperidine derivatives of WO 93/14084 are intended for the treatment of inflammatory diseases of the skin such as herpes, which is an viral infectious disease, or eczema, which is an immunological disease.

That is to say that the documents are each directed to the treatment of **pathological** disorders showing **inflammatory and immunological** conditions. It is commonly known, however, that inflammation is characterized by the simultaneous presence of four clinical symptoms, namely, redness, heat, edema and pain (e.g., rubor, calor, tumor, and dolor). Furthermore, it is well understood in the art that pain is not the same thing as discomfort and that inflammation is always characterized *inter alia* by edema (i.e., swelling). In stark contrast, however, the claimed methods are directed to the treatment of a **non-pathological** condition, namely, sensitive skins and dysesthesia.

7) The characteristic features of sensitive skin are, of course, described in the pending application as are the symptoms and triggering factors. The fact that some sensitive skin manifestation may also be observed and associated with some other disease does not render the claimed methods anticipated by or obvious over references that describe methods for the treatment of such other diseases. Moreover, it is well known that a physiological or pathological state can only be defined by taking into account all parameters together. A specific state can only be established through a complete "clinical table" encompassing essential and characteristic features of the state. The mere observation of a single and isolated

sign in a particular subject is not enough to characterize the specific state. More importantly, it is well understood that the specific state of sensitive skin is not equivalent to inflammation. Notably, as described in the present application, edema is never a sign of sensitive skin.

8) In view of the above, it is my opinion that the cited references cannot be relied on to support an anticipation or obviousness rejection because they do not disclose or fairly suggest treating sensitive skin. These references simply describe methods of treating skin diseases, which may exhibit occasionally one isolated sign associated to sensitive skin.

9) To further support the description of sensitive skin provided in the application, and in an effort to help the Examiner understand that the methods described in the cited references for treating pathological disorders exhibiting a symptom of inflammation are distinguished from the claimed methods of treating the non-pathological disorder sensitive skin, I have attached a first study that shows that even if the manifestations of sensitive skin are infraclinic, sensitive skin is a real state (see Appendix II). In the attached the study, I conducted an analysis of cerebral activity and found that brain activation was induced by discomfort sensory stimuli in people with sensitive skin.

The study further demonstrates that the non-pathological condition of sensitive skin unlike the pathological conditions being treated in the cited references is a **non-inflammatory** condition. The study demonstrates that skin reactivity to lactic acid on the same group of individuals and during the same study enabled us to differentiate between people with sensitive skin and those with non-sensitive skin. (See, for example, Point 6 and the Conclusion.) Furthermore, the study proved that people with sensitive skin do not have inflamed skin. Surprisingly, we were able to define and characterize a new group of individuals presenting a group of specific signs distinct from those seen in inflammation and allergy. In contrast, prior to the filing of our application, the problem of sensitive skin was not understood because it was poorly characterized. In addition, no specific treatment had been proposed to address this problem. Because the cited references provide no disclosure or

suggestion of our discoveries, the cited references cannot be said to anticipate or render obvious the claimed methods of treatment.

10) Furthermore, I have attached slide presentation of a second study (see Appendix III, corresponding to the below Communication ref. 100) that first states that 51% of European and American women show sensitive skin. This rate is too high to be a pathological state, a pathological state being defined by the frequency and the gravity of the disorder it involves compared to a normal state. This study further states that no link between contact dermatitis and immunoallergologic disease, or respiratory allergens and sensitive skin may be established.

11) Based on the attached sensitive skin study and the above comments, and my 10 years of research in the field of dermatophysiology, it is my professional opinion that the claimed methods are neither anticipated nor rendered obvious by the cited prior art references. The cited references disclose methods of treating pathological conditions; they do not disclose or fairly suggest methods for treating the non-pathological condition sensitive skin. In addition, while the individuals being treated in the cited references may be experiencing a symptom of inflammation, I submit, and the attached study proves, that the individuals in the cited references being treated for pathological disorders are not individuals who are necessarily in need of the claimed methods for treating the non-pathological condition of sensitive skin. Indeed, the **pathological inflammatory conditions** being treated in the cited references are different from the **non-pathological/non-inflammatory condition** of sensitive skin. Certainly, it cannot be shown that the individuals in the cited references being treated for these other pathological/inflammatory conditions are necessarily individuals with sensitive skin having an amount of substance P released therein to cause neurogenic manifestations of dyesthesia, as claimed. Moreover, there is no disclosure or suggestion in the cited references that the described methods for treating other diseases would be useful to treat sensitive skin. For at least these reasons, I respectfully request the Examiner's reconsideration and withdrawal of the outstanding rejections.

I HEREBY DECLARE that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be

true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 23 mars 2006

Olivier de Lacharrière

Olivier De Lacharrière

APPENDIX I

APPENDIX I

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EXPERIENCE

1994-Present : Director of Prospective Clinical Research, L'Oréal Research

1994-Present: Dermatogist consultant at Assistance Publique-Hôpitaux de Paris

1988-1994 : Chairman of Department of Internal Medecine, Hôpital Corentin Celton, Assistance Publique-Hôpitaux de Paris, Issy les Moulineaux, France.

1984-1988 : Internist, Dermatologist, Head Clinical Assistant
Faculté de Médecine Necker Enfants-Malades, Paris, France

1979-1984 : Resident in Internal Medecine and Dermatology
Fellow of Paris Hospitals (Interne des Hôpitaux de Paris)

ACADEMIC POSITIONS

2000- Present: Visiting Professor in Dermatology, China Medical University

1999- Present: Professor Associate in Dermatology, Suzhou Medical College, China

1994-Present : Lecturer at Institut Jacques Monod, Paris V, France

1988-1994 : Lecturer at Faculté de Médecine Necker Enfants-Malades, Paris V

1984-1988 : Assistant Professor of Dermatology, René Descartes University, Paris V, France

EDUCATION

1982 : M.D, René Descartes University, Paris V
Laureate of Faculté de Médecine Necker Enfants-Malades

1986 : Specialist in Internal Medecine, René Descartes University, Paris V
Specialist in Dermatology, René Descartes University, Paris V

1989 : Genetics and Cellular Biology, Institut Pasteur, Paris

SCIENTIFIC SOCIETIES

Société Française de Dermatologie (since 1987)
Société Française de Recherche Dermatologique (since 1988)
Société Française de Gérontologie (since 1992)
Société Francophone de Dermatologie Psychosomatique (since 1992)
European Society for Dermatological Research (since 1993)
Société Francophone de Bio-ingénierie Cutanée (since 1999).

PUBLICATIONS

More than 60 publications, 100 communications and 50 patent applications.

PUBLICATIONS
(O. de LACHARRIERE – juin 2005)

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6. Microcirculation cutanée : Aspects physiologiques - Méthodes d'explorations.
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11. Microcirculation cutanée - Données physiologiques et méthodes d'exploration.
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COMMUNICATIONS (O. de LACHARRIERE – juin 2005)

1. Léiomyomatose cutanée multiple ; Traitement par la phenoxybenzamine.
   P.Y. VENENCIE, P. BIGEL, O. de LACHARRIERE, V. LEMONIER, D. THEBAUD-GERBAUD, JH. SAURAT.
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